DAVID Y. IGE GOVERNOR OF HAWAII



VIRGINIA PRESSLER, M.D. DIRECTOR OF HEALTH

STATE OF HAWAII DEPARTMENT OF HEALTH P. O. Box 3378 Honolulu, HI 96801-3378 doh.testimony@doh.hawaii.gov

WRITTEN ONLY

Testimony in SUPPORT of SB1032, SD1 RELATING TO CHAPTER 245, HAWAII REVISED STATUTES

SENATOR JILL N. TOKUDA, CHAIR SENATE COMMITTEE ON WAYS AND MEANS Hearing Date: February 27, 2015 Room Number: 211

1 Fiscal Implications: The Department of Health (DOH) defers to the Department of Taxation

2 (DoTAX) on the fiscal implications.

3 **Department Testimony:** The DOH supports the significant increase in licensure and permitting

4 fees which have remained unchanged since 1995 despite high tobacco taxes and ever increasing

5 tobacco industry expenditures in marketing and advertising. Tobacco licensing is an effective

6 tool for limiting the negative public health consequences of tobacco use by ensuring that

7 wholesalers and retailers comply with responsible sales practices.

8 The current license fee for tobacco wholesalers and dealers in Hawaii is \$2.50. An 9 analysis of tobacco sales license requirements across the United States reveals a very broad range 10 of fees for different statutory purposes. The amounts vary from no fee at all to \$1,500.00/year. 11 Of the 40 states that do have fees, 26 states charge \$100.00/year or more and 14 states charge 12 \$200.00/year or more. Nine states charge between \$500.00/year and \$1,500.00/year. Hawaii is 13 only one of two states that charge a wholesaler less than a retailer.

The retail tobacco permit was instituted in 2006 and DoTAX is the issuer of the annual \$20.00 fee. The purpose of the fee is to cover administrative costs. Nationally, the amounts vary from no fee to \$1,000.00/year. Of the 32 states that have retailer fees, 15 states charge more than \$20.00/year but less than \$100.00/year, with about half (8 out of 15) of those states charging \$50.00/year or more.

Licensure fees should cover all related administrative expenses to the license. DoTAX
sends out notices, reviews applications, conducts billing, collects fees, and maintains the
database. It further has the authority to suspend or revoke licenses and permits for failure to

- 1 comply with the law.
- 2 **Offered Amendments:** No amendments are requested.
- 3 Thank you for the opportunity to testify.

SHAN TSUTSUI LT. GOVERNOR



STATE OF HAWAII **DEPARTMENT OF TAXATION** P.O. BOX 259 HONOLULU, HAWAII 96809 PHONE NO: (808) 587-1540 FAX NO: (808) 587-1560

To: The Honorable Jill N. Tokuda, Chair and Members of the Senate Committee on Ways and Means

Date:Friday, February 27, 2015Time:1:00 P.M.Place:Conference Room 211, State Capitol

From: Maria E. Zielinski, Director Department of Taxation

Re: S.B. 1032, S.D. 1, Relating to Chapter 245, Hawaii Revised Statutes

The Department of Taxation (Department) provides the following comments on S.B. 1032, S.D. 1 for your consideration, and defers to the Department of Health regarding the merits of this measure.

S.B. 1032, S.D. 1 amends the Cigarette Tax and Tobacco Tax Law by taxing non-tobacco nicotine-containing products at a rate of 70% of the wholesale price of such items. This measure also raises the yearly tobacco wholesaler or producer license fee from \$2.50 to \$250, and raises the yearly retail tobacco permit from \$20 per retail location to \$50 per retail location. S.D.1 is effective January 1, 2016.

The previous committee adopted all of the Department's suggested amendments to the previous version of this bill. The Department appreciates consideration of its suggested amendments.

Thank you for the opportunity to provide comments.



Legislative Testimony

Written Testimony Presented Before the Senate Committee on Ways and Means February 27, 2015 at 1:00 pm By Robert Bley-Vroman, Chancellor and Jerris Hedges, MD, MS, MMM Dean, John A. Burns School of Medicine Interim Director, University of Hawai'i Cancer Center University of Hawai'i at Mānoa

SB 1032 SD1 – RELATING TO CHAPTER 245, HAWAII REVISED STATUTES

Chair Tokuda, Vice Chair Kouchi, and Members of the Committee:

The University of Hawai'i Cancer Center supports this bill.

The UH Cancer Center is one of only 68 institutions in the U.S. that hold the prestigious National Cancer Institute (NCI) designation, and is the only NCI-designated center in the Pacific. The NCI designation provides greater access to federal funding and research opportunities. More importantly, it gives the people of Hawai'i and the Pacific region access to innovative and potentially life-saving clinical trials without the necessity of traveling to the mainland.

Our passion at the UH Cancer Center is to be a world leader in eliminating cancer through research, education and improved patient care. Because tobacco consumption is a leading preventable cause of cancer, we take all issues related to tobacco in Hawai'i very seriously. Whereas the UH Cancer Center always has supported strong tobacco control measures in Hawai'i, the recent emergence of electronic smoking devices presents new challenges for tobacco control and tobacco-related legislation.

The UH Cancer Center perspective on electronic smoking devices is informed by the scientific literature, including original published research by our own faculty. For example, UH Cancer Center researcher Thomas Wills, PhD, uncovered a growing public health problem among Hawai'i's youth by showing Hawai'i teens used e-cigarettes at nearly triple the rate of mainland teens. His study in the journal *Pediatrics* further showed that e-cigarettes use was growing nationally among teens.

Despite the complexities of the larger debate regarding electronic smoking devices, we believe this bill represents reasonable legislation that balances the rights of adults to use electronic smoking devices in appropriate venues while restricting the use of electronic smoking devices in public places where conventional cigarettes are banned. We also support the prohibition of the sale of electronic smoking devices to minors, and we support the provisions in this bill that enhance the ability of authorities to enforce these laws.

As scientific research on electronic smoking devices progresses, we will have a stronger basis to adjust laws according to evidence. At the present time, however, caution is warranted. As others have noted, the FDA currently does not regulate electronic smoking devices, and thus the consumer has no assurances regarding electronic smoking device ingredients. Further, because of the novelty of electronic smoking devices, the long term effects of using these devices are unknown. A further concern, not often discussed, is the potential for electronic smoking devices to be used as drug delivery devices for substances other than nicotine.

We respectfully urge you to pass this bill.



American Cancer Society Cancer Action Network 2370 Nu`uanu Avenue Honolulu, Hawai`i 96817 808.432.9149 www.acscan.org

Senate Committee on Ways and Means Senator Jill Tokuda, Chair Senator Ron Kouchi, Vice Chair

Decision Making: February 27, 1:00 pm

SB 1032, SD1 – RELATING TO CHAPTER 245, HAWAII REVISED STATUTES

Cory Chun, Government Relations Director – Hawaii Pacific American Cancer Society Cancer Action Network

Thank you for the opportunity to provide written comments in support of SB 1032, SD1, which increases the fees for tobacco wholesalers and retailers in the State.

The American Cancer Society Cancer Action Network (ACS CAN) is the nation's leading cancer advocacy organization. ACS CAN works with federal, state, and local government bodies to support evidence-based policy and legislative solutions designed to eliminate cancer as a major health problem.

The current fee is \$2.50 for a tobacco wholesaler or distributor and \$20 for tobacco retailers, which are low considering the products that are being sold and distributed. Considering that nature of the products sold, the current fees do not accurately reflect the danger that these products pose to individuals from the sale of these products.

To put these fee increases into perspective, the statutory fees for the sale of fireworks in the State are significantly higher. Section 132D-11, Hawaii Revised Statutes, lists the license fees as \$3,000 for importers, \$2,000 for each wholesaler's site, \$1,000 for each storage site, and \$500 for each retailer's site. In comparison to these fees, the increases proposed by this measure are significantly lower than fees paid for the privilege to sell fireworks. We feel that the increase in fees for tobacco wholesalers and retailers are reasonable when compared to other license fees for hazardous consumer products sold in our State.

Thank you for the opportunity to submit comments on this matter.



Testimony in SUPPORT of SB 1032, SD1, "Relating to Chapter 245, Hawaii Revised Statutes"

The permitting, and threat of loss of a permit to sell tobacco, can be an effective deterrent to those who would illegally sell tobacco products to a minor. It is one part of a scientifically-based, comprehensive effort that has been proven to help reach the goal of reducing youth access to tobacco. It also provides the Attorney General's office with an important tool to identify locations selling tobacco to insure that those retailers pay the appropriate taxes on their sales.

In recent years, there has been an upward trend among Hawaii teens to use electronic smoking devices, with the number of teens using those products tripling in just the last several years. This trend has occurred despite state legislation restricting the sale of those devices to minors. Clearly there is a need for better enforcement of that law. SB 1032, SD1 would help Hawaii's law enforcement officers to identify those selling electronic smoking devices both legally and illegally, and help to keep those products out of the hands of minors. The American Heart Association also believes that electronic smoking devices should be defined and regulated as tobacco products.

Tobacco use remains the leading cause of preventable death in the United States, killing more than 400,000 people each year. It is known to cause heart disease, stroke, cancer, and respiratory diseases, among other health disorders, and costs the U.S. \$96 billion in health care expenditures each year. Nearly 1,000 kids under the age of 18 become regular, daily smokers each day; and almost one-third will die from it. Most smokers begin their nicotine addiction as a teen or youth.

The American Heart Association feels that making the requirement to obtain a permit to sell all tobacco-related products, as proposed by SB 1032, SD!, would provide a strong deterrent to those who might purposely, or accidentally, sell tobacco products to minors. It would encourage retailers to be more vigilant in insuring that their sales staff is trained in checking for appropriate age identification when selling tobacco products.

In addition, Hawaii's current tobacco retailer licensing fee is among the lowest in the country and should be increased to reflect the harm caused by the products being licensed for sale. The American Heart Association recommends that increased revenue resulting from such an increase in licensing should be earmarked for programs designed to support tobacco prevention, control and cessation.

Thank you for this opportunity to provide testimony in SUPPORT of SB 1032, SD1.

Respectfully submitted,

rold B. Wersmon

Donald B. Weisman Hawaii Government Relations Director

life is whv[∞]

"Building healthier lives, free of cardiovascular diseases and stroke."

es por la vida Please remember the American Heart Association in your will.

全为生命。



To: The Honorable Jill N. Tokuda, Chair, Committee on Ways and Means The Honorable Ronald D. Kouchi, Vice Chair, Committee on Ways and Means Members, Senate Committee on Ways and Means

From: Lyndsey Garcia, Policy & Advocacy Director

Date: February 26, 2015

Hrg: Senate Committee on Ways and Means; Friday, February 27, 2015 at 1:00PM in Rm 211

Re: Support for SB 1032, SD1, Relating to Chapter 245, Hawai'i Revised Statutes

Thank you for the opportunity to offer testimony in **support** of Senate Bill 1032, SD1, which increases the license fee for a person engaged as a wholesaler or dealer of cigarettes or tobacco products and increases the retail tobacco permit fee for retailers engaged in the retail sale of cigarettes and other tobacco products.

The Coalition for a Tobacco Free Hawai`i (Coalition) is a program of the Hawai`i Public Health Institute working to reduce tobacco use through education, policy and advocacy. Our program consists of over 100 member organizations and 2,000 advocates that work to create a healthy Hawai`i through comprehensive tobacco prevention and control efforts.

The Coalition supports increasing the wholesaler and dealer license fee to \$250.00.

After state by state research on license fees for wholesalers, dealers, and distributors, the Coalition finds that of all the states that charge a wholesale and dealer license fee, Hawai`i has the lowest wholesaler and dealer license fee in the nation at \$2.50.

Nationally, the amounts range from no fee to \$1,500.00 per year. Of the 38 states that have fees, Hawai`i has the lowest fee. Most states (26 out of 38) charge \$100.00 per year or more. 14 states charge \$200.00 per year or more and nine states charge between \$500.00 per year and \$1,500.00 per year. Hawai`i is the only state that charges a wholesaler less than a retailer. Comparatively, the City and County of Honolulu Liquor Commission charges \$2,640.00 annually for a Wholesale General Standard liquor license.

The Coalition supports increasing the retail tobacco permit fee to \$50.00.

After state by state research on permit fees for retailers, the Coalition finds that of all the states that charge a retail tobacco permit fee, Hawai`i currently has one of the lowest retailer permit fees in the nation at \$20.00.

Nationally, the amounts range from no fee to \$1,000.00 per year. Of the 32 states that charge a retailer permit fee, 15 states charge more than \$20.00 per year but less than \$100.00 per year, with about half of those states charging \$50.00 per year or more. The average amount charged is \$83.75 per year. Comparatively, the City and County of Honolulu Liquor Commission charges \$1,200.00 annually for a Retail General Standard liquor license.



The Coalition supports SB 1032, SD1 and respectfully asks you to pass this measure. Thank you for the opportunity to testify on this matter.

Respectfully,

ydsy Jaiaa

Lyndsey Garcia Policy and Advocacy Director



To: The Honorable Jill N. Tokuda, Chair and Members of the Senate Committee on Ways and Means
Date: Friday, February 27, 2015
Time: 1:00 p.m.
Place: Conference Room 211, State Capitol
From: Les Drent for the Hawaii Cigar Association
Re: SB1032 SD1, Relating To Chapter 245, Hawaii Revised Statutes

Dear Senator Jill N. Tokuda, Chair and Members of the Senate Committee on Ways and Means,

The Hawaii Cigar Association (HCA) respectfully **OPPOSES** this measure for the following reasons:

1. The unreasonable and enormous increase of the tobacco wholesalers license from \$2.50 to \$250, and the increase of the retail tobacco permit from \$5.00 to \$50.00 will unnecessarily harm small businesses in Hawaii. The vast majority of licensed tobacco wholesalers, and retailers currently abide by the rules and regulations under chapter 245, Hawaii Revised Statutes.

2. The increased fees will not further the enforcement of the law in regards to cigars, since the majority of these tobacco products are obtained by Hawaii residents through mail order from unlicensed entities outside of the state. A simple solution to ensure tobacco regulation, and the collection of tax revenue would be to enact a tax cap on large cigars, and create parity in the tax code. Unless Hawaii cigar retailers are able to compete with foreign businesses, any increase in licensing fees makes little sense. Under this proposal the sale of cigars from unlicensed sources would increase, and tax revenue would decrease.

Respectfully submitted,

Les Drent for the Hawaii Cigar Association

For More Information on the Hawaii Cigar Association please visit

hawaiicigarassociation.org



Executive Officers: John Schilf, RSM Hawaii - Chairperson Derek Kurisu, KTA Superstores - Vice Chair Lisa DeCoito, Aloha Petroleum - Treasurer John Erickson, Frito-Lay - Secretary Lauren Zirbel, Executive Director

1050 Bishop St. PMB 235 Honolulu, HI 96813 Fax : 808-791-0702 Telephone : 808-533-1292

TO: COMMITTEE ON WAYS AND MEANS Senator Jill N. Tokuda, Chair Senator Ronald D. Kouchi, Vice Chair

FROM: HAWAII FOOD INDUSTRY ASSOCIATION Lauren Zirbel, Executive Director

DATE:	February 27, 2015
TIME:	1pm
PLACE:	Conference Room 211

RE: SB1032

Position: Oppose

The Hawaii Food Industry Association is comprised of two hundred member companies representing retailers, suppliers, producers, and distributors of food and beverage related products in the State of Hawaii.

While we appreciate that the removal of one problematic part of this bill it still has a number of issues that make it unsuitable for passage.

First of all, the fact that electronic smoking devices look similar to cigarettes and can also contain nicotine is not sufficient reason to change the regulatory definition of "tobacco products" and add additional fees and taxes to these products. Electronic smoking devices do not contain tobacco and are not tobacco products. Smoking cessation products, which also contain nicotine, are not subject to the same regulations and taxes as cigarettes. This suggests that the primary reason for including electronic smoking devices in the definition of "tobacco products" is that they physically resemble cigarettes. The physical resemblance of one product to another is not a sufficient reason to impose a costly and burdensome regulatory and tax structure, which will negatively impact wholesalers, retailers, and consumers.

Secondly, Hawaii has the second highest tobacco taxes of any state. By attempting to increase the fees as well this bill unfairly targets retailers and wholesalers, rather than focusing efforts on tobacco users.

Finally, retailer license fees exist to pay for the licensing process and enforcement, not as a tool for public health. The existing fees should be sufficient to cover their intended purposes and attempts to increase them to support other goals sets a bad precedent.

For these reasons we ask that you defer this measure indefinitely. Thank you for the opportunity to testify.



То:	The Honorable Jill N. Tokuda, Chair and Members of the Senate Committee on Ways and Means
Date: Time: Place:	Friday, February 27, 2015 1:00 p.m. Conference Room 211, State Capitol
From:	Les Drent for Kauai Cigar Company
	Re: SB1032 SD1, Relating To Chapter 245, Hawaii Revised Statutes

Dear Senator Jill N. Tokuda, Chair and Members of the Senate Committee on Ways and Means,

The Kauai Cigar Company, its 23 Hawaii based employees, and industry partners <u>OPPOSE</u> this measure.

Without any limit or cap on cigar taxes, our company already pays more taxes per cigar than any other manufacturer selling its products within the state. To increase the licensing fees for businesses that sell our products would be damaging to our company. The vast majority of Hawaii cigar aficionados already purchase their cigars from foreign unlicensed businesses. These added license fees would only encourage more customers to purchase their cigars through mail order, and online sources.

Without parity in the tax code, any increase in fees, or taxes makes little sense.

Respectfully submitted,

Les Drent Farmer/President

Kauai Cigar Company 6200 Kawaihau Road, Unit B, Kapaa, HI 96746 USA Ph: 808-822-4495 Fax: 808-822-9731



CAP THE CIGAR TAX!

Create Fairness and Equal Opportunity for Hawaii Businesses

50¢ Cigar Tax From Other US States:

Connecticut	Iowa	Oregon	Rhode Island	Arkansas
Washington	Michigan	Wisconsin	Vermont	
US Government (40¢)	New Hampshire	(00.00 on premiun	n cigars)	

Current HAWAII LAW (50% of wholesale price)

§245-3 Taxes.

(13) An excise tax equal to **fifty per cent** of the wholesale price of each large cigar of any length, sold, used, or possessed by a wholesaler or dealer on and after September 30, 2009, whether or not sold at wholesale, or if not sold then at the same rate upon the use by the wholesaler or dealer.

EXAMPLE of OREGON CAP LAW- TOBACCO TAXES (CIGARS)

323.505

Tax imposed on distribution; rate. (1) A tax is hereby imposed upon the distribution of all tobacco products in this state. The tax imposed by this section is intended to be a direct tax on the consumer, for which payment upon distribution is required to achieve convenience and facility in the collection and administration of the tax. The tax shall be imposed on a distributor at the time the distributor distributes tobacco products. (2) The tax imposed under this section shall be imposed at the rate of:

(a) Sixty-five percent of the wholesale sales price of cigars, but not to exceed 50 cents per cigar;

EXAMPLE OF NEW HAMPSHIRE PREMIUM CIGAR DEFINITON

78:1 "Premium cigars" means cigars which are made entirely by hand of all natural tobacco leaf, hand constructed and hand wrapped, wholesaling for \$2.00 or more, and weighing more than 3 pounds per 1,000 cigars. These cigars are required to be kept in a humidor.

For More Information on the Hawaii Cigar Association please visit

hawaiicigarassociation.org

February 26, 2015

To: The Honorable Rosalyn H. Baker, Nishihara, Ruderman, Espero, Wakai

From: Cory Smith, VOLCANO Fine Electronic Cigarettes[®] CEO and Owner

RE: SB1032 - oppose.

Thank you for the opportunity to submit testimony.

VOLCANO Fine Electronic Cigarettes[®] is the largest manufacturer and retailer of vapor products and vaping accessories in the State of Hawaii. We currently own and operate 11 locations statewide and employ over 100 full-time workers to support sales of our products not only here in Hawaii, but to all 50 states as well as Japan and the UK. We stand in opposition to HB349 for the following:

• Although vapor products contain NO tobacco, often times contain NO nicotine, and ultimately emit NO smoke, SB1032 aims to unfairly classify all vapor products as "Tobacco Products" to bring vapor products into the same regulatory framework as traditional tobacco cigarettes. This will have very dire unintended consequences and threatens to decimate the vapor industry in Hawaii.

• Although the FDA has stated its intention to regulate vapor products under the Tobacco Control Act of 2009, they still have not released a final rule due to the many nuances at play. Recently, leaders in the national House of Representatives went as far as to request changes by the Department of Health and Human Service to the Tobacco Control Act that would create special rules for vapor products due to their vast differences with traditional tobacco cigarettes. These leaders see the trouble with including vapor products in a regulatory framework that was never built with them in mind and we are wary that the same issue is being presented with this bill.

http://www.churnmag.com/news/house-leaders-urge-fda-go-easy-ecigs/

• Vapor products have not been demonstrated to have the same detrimental effects of combustible tobacco products and thus should not be regulated under the same framework. In fact, Mitch Zeller, Director of the Center for Tobacco Products at the FDA recently stated:

• "If a current smoker, otherwise unable or unwilling to quit, completely substituted all of the combusting cigarettes that they smoked with an electronic cigarette at the individual level, that person would probably be significantly reducing their risk."

http://thedianerehmshow.org/shows/20140121/newhealthriskscigarettesmoking/transcript

• SB1032 exempts traditional NRT products that contain nicotine even though electronic cigarettes are being shown to be a much more effective tool for helping

people quit smoking and have been demonstrated to have a similar risk profile.

It is our belief that this unjustified product classification is in the best interest of no one in the state of Hawaii. Thank you for your time and consideration. If you have any questions, please feel free to contact me or Volcano's representative Celeste Nip at n ipfire@me.com.

Sincerely, Cory Smith CEO and Owner VOLCANO Fine Electronic Cigarettes®

1003 Sand Island Access Rd. Suite #1260, Honolulu, HI 96813

RESEARCH REPORT doi:10.1111/add.12623

Real-world effectiveness of e-cigarettes when used to aid smoking cessation: a cross-sectional population study

Jamie Brown^{1,2}, Emma Beard¹, Daniel Kotz^{1,3}, Susan Michie^{2,4} & Robert West^{1,4}

Cancer Research UK Health Behaviour Research Centre, University College London, London, UK,¹ Department of Clinical, Educational and Health Psychology, University College London, London, UK,² Department of Family Medicine, CAPHRI School for Public Health and Primary Care, Maastricht University Medical Centre, Maastricht, the Netherlands³ and National Centre for Smoking Cessation and Training, London, UK⁴

ABSTRACT

Background and Aims Electronic cigarettes (e-cigarettes) are rapidly increasing in popularity. Two randomized controlled trials have suggested that e-cigarettes can aid smoking cessation, but there are many factors that could influence their real-world effectiveness. This study aimed to assess, using an established methodology, the effectiveness of e-cigarettes when used to aid smoking cessation compared with nicotine replacement therapy (NRT) bought over- the-counter and with unaided quitting in the general population. **Design and Setting** A large cross-sectional survey of a representative sample of the English population. Participants The study included 5863 adults who had smoked within the previous 12 months and made at least one quit attempt during that period with either an e-cigarette only (n = 464), NRT bought over-the-counter only (n = 464)1922) or no aid in their most recent quit attempt (n = 3477). Measurements The primary outcome was self-reported abstinence up to the time of the survey, adjusted for key potential confounders including nicotine dependence. Findings E-cigarette users were more likely to report absti- nence than either those who used NRT bought over-thecounter [odds ratio (OR) = 2.23,95% confidence interval (CI) = 1.70-2.93,20.0 versus 10.1%] or no aid (OR = 1.38, 95% CI = 1.08-1.76, 20.0 versus 15.4%). The adjusted

odds of non-smoking in users of e-cigarettes were 1.63 (95% CI = 1.17-2.27) times higher compared with users of NRT bought over-the-counter and 1.61 (95% CI = 1.19-2.18) times higher compared with those using no aid. **Conclusions** Among smokers who have attempted to stop without professional support, those who use e-cigarettes are more likely to report continued abstinence than those who used a licensed NRT product bought over-the-counter or no aid to cessation. This difference persists after adjusting for a range of smoker characteristics such as nicotine dependence.

Keywords Cessation, cross-sectional population survey, e-cigarettes, electronic cigarettes, nicotine replacement therapy, NRT, quitting, smoking.

Correspondence to: Jamie Brown, Health Behaviour Research Centre, Department of Epidemiology and Public Health, University College London, 1-19 Torrington Place, London WC1E 6BT, UK. E-mail: jamie.brown@ucl.ac.ukSubmitted 27 February 2014; initial review completed 8 April 2014; final version accepted 12 May 2014

INTRODUCTION

Smoking is one of the leading risk factors for premature death and disability and is estimated to kill 6 million people world-wide each year [1]. The mortality and morbidity associated with cigarette smoking arises primarily from the inhalation of toxins other than nicotine contained within the smoke. Electronic cigarettes (e-cigarettes) provide nicotine via a vapour that is drawn into the mouth, upper airways and possibly lungs [2,3].

These devices use a battery-powered heating element activated by suction or manually to heat a nicotine solu- tion and transform it into vapour. By providing a vapour containing nicotine without tobacco combustion, e-cigarettes appear able to reduce craving and with-drawal associated with abstinence in smokers [2,4,5], while toxicity testing suggests that they are much safer to the user than ordinary cigarettes [3].

E-cigarettes are increasing rapidly in popularity: prevalence of ever-use among smokers in the United

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4

1532 Jamie Brown et al.

States appears to have increased from approximately 2% in 2010 to more than 30% in

2012, and the rate of increase appears to be similar in the United Kingdom [6–9]. Although there are concerns about their wider public health impact relating to the renormalization of smoking and promotion of smoking in young people, cru- cially two randomized controlled trials have suggested that e-cigarettes may aid smoking cessation [10,11]. However, there are many factors that influence real- world effectiveness, including the brand of e-cigarette, the way they are used and who chooses to use them [12]. Therefore, it is a challenge to establish probable contribu- tion to public health through randomized efficacy trials alone. Moreover, this kind of evidence will take many years to emerge, and in the meantime the products are developing rapidly and countries require evidence on effectiveness to inform decisions on how to regulate them [13–19]. As a result, there is an urgent need to be able to make an informed judgement on the real-world effective- ness of currently popular brands as chosen by the mil- lions of smokers across the world who are using them in an attempt to stop smoking [6–9].

Several studies have attempted to examine the rela- tionship between the use of ecigarettes and smoking status in the real world by surveying regular e-cigarette users [20-27]. These studies—including one using a lon-gitudinal design [27]—have found that users consistently report that e-cigarettes helped them to quit or reduce their smoking. However, because the samples were self- selected, the results have to be interpreted with caution. In more general samples the evidence is less positive. One national study of callers to a quitline, which assessed the cross-sectional association of e-cigarette use and current smoking status at a routine follow-up evaluation of the quitline service, found that e-cigarette users compared with never users were less likely to be abstinent [28]. In a longitudinal study of a general population sample, e-cigarette users at baseline were no more likely to have quit permanently at a 12-month follow-up despite having reduced their cigarette consumption [29]. However, neither of these studies adjusted for important potential confounding variables and both evaluated the associa- tion between quitting and the use of e-cigarettes for any purpose, not specifically as an aid to quitting. It is crucial to distinguish between the issue of whether use of e-cigarettes in a quit attempt improves the chances of success of that attempt from the issue of whether the use of e-cigarettes, for whatever purpose, such as aiding smoking reduction or recreation, promotes or suppresses attempts to stop. In determining the overall effect on public health both considerations are important, but they require different methodologies to address them.

An ongoing national surveillance programme (the Smoking Toolkit Study) has been tracking the use of

e-cigarettes as a reported aid to cessation among the general population in England since July 2009 [30]. This programme has established a method of assessing real- world effectiveness of aids to cessation by comparing the success rates of smokers trying to quit with different methods and adjusting statistically for a wide range of factors that could bias the results, such as nicotine dependence [31]. The method has been able to detect effects of behavioural support and prescription medica- tions to aid cessation and found a higher rate of success when using varenicline than prescription nicotine replacement therapy (NRT) [32,33], supporting findings from randomized controlled trials and clinical observa- tion studies [34–37]. This method cannot achieve the same level of internal validity as a randomized controlled trial, but clearly has greater external validity, so both

are important in determining the potential public health con- tribution of devices hypothesized to aid cessation, such as e-cigarettes.

Given that smokers already have access to licensed NRT products, it is important to know whether e-cigarettes are more effective in aiding quitting. This comparison is particularly important for two reasons. First, buying a licensed NRT product from a shop, with no professional support, is the most common way of using it in England, and secondly, previous research has found that this usage was not associated with greater success rates than quitting unaided in the real-world [33]. It is therefore important to know whether e-cigarettes can increase abstinence compared to NRT bought over-the-counter.

The current study addressed the question of how effective e-cigarettes are compared with NRT bought over-the-counter and unaided quitting in the general population of smokers who are attempting to stop.

METHODS

Study design

The design was cross-sectional household surveys of rep- resentative samples of the population of adults in England conducted monthly between July 2009 and Feb- ruary 2014. To examine the comparative real-world effectiveness of e-cigarettes, the study compared the self- reported abstinence rates of smokers in the general popu- lation trying to stop who used e-cigarettes only (i.e. without also using face-to-face behavioural support or any medically licensed pharmacological cessation aid) with those who used NRT bought over-the-counter only or who made an unaided attempt, while adjusting for a wide range of key potential confounders. The surveys are part of the ongoing Smoking Toolkit Study, which is designed to provide information about smoking

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prevalence and behaviour in England [30]. Each month a new sample of approximately 1800 adults aged ≥ 16 years are selected using a form of random location sam- pling, and complete a face-to-face computer-assisted survey with a trained interviewer. The full methods have been described in detail and shown to result in a sample that is nationally representative in its socio-demographic composition and proportion of smokers [30]. Approval was granted by the ethics committee of University College London, UK.

Study population

For the current study, we used aggregated data from respondents to the survey in the period from July 2009 (the first wave to track use of e-cigarettes to aid cessation) to February 2014 (the latest wave of the survey for which data were available), who smoked either cigarettes (including hand-rolled) or any other tobacco product (e.g. pipe or cigar) daily or occasionally at the time of the survey or during the preceding 12 months. We

included those who had made at least one quit attempt in the pre- ceding 12 months, assessed by asking: 'How many serious attempts to stop smoking have you made in the last 12 months? By serious attempt I mean you decided that you would try to make sure you never smoked again. Please include any attempt that you are currently making and please include any successful attempt made within the last year'. We included respondents who used either e-cigarettes or NRT bought over-the-counter during their most recent quit attempt, and an unaided group defined as those who had not used any of the fol- lowing: e-cigarettes; NRT bought over-the-counter; a pre- scription stop-smoking medication; or face-to-face behavioural support. We excluded those who used either e-cigarettes or NRT bought over-the-counter in combina- tion with one another, a prescription stop-smoking medi- cation or face-to-face behavioural support.

Measurement of effect: quitting method

The use of different quitting methods were assessed for the most recent attempt by asking: 'Which, if any, of the following did you try to help you stop smoking during the most recent serious quit attempt?' and included: (i) e-cigarettes; (ii) NRT bought over-the-counter; (iii) no aid (i.e. had not used any of e-cigarettes, NRT bought over- the-counter, a prescription stop-smoking medication or face-to-face behavioural support).

Measurement of outcome: self-reported non-smoking

Our primary outcome was self-reported non-smoking up to the time of the survey. Respondents were asked: 'How long did your most recent serious quit attempt last before

you went back to smoking?'. Those responding 'I am still not smoking' were defined as non-smokers. Previous research has shown that self-reported abstinence in surveys of this kind is not subject to the kind of biases observed in clinical trials where there is social pressure to claim abstinence [38].

Measurement of potential confounders

We measured variables potentially associated with the different quitting methods and that may also have an effect on the outcome. These potential confounders were chosen a priori. The most important factor was nicotine dependence, for which we used two questions. First, time spent with urges to smoke was assessed by asking all respondents: 'How much of the time have you felt the urge to smoke in the past 24 hours? Not at all (coded 0), a little of the time (i), some of the time (ii), a lot of the time (iii), almost all of the time (iv), all of the time (v)'. Sec- ondly, strength of urges to smoke was measured by asking: 'In general, how strong have the urges to smoke been? Slight (i), moderate (ii), strong (iii), very strong (iv), extremely strong (v)'. This question was coded '0' for smokers who responded 'not at all' to the previous ques- tion. In this population these two ratings have been found to be a better measure of dependence (i.e. more closely associated with relapse following a quit attempt) than other measures [32,33,39]. The demographic char- acteristics assessed were age, sex and social grade (dichotomized into two categories: ABC1, which includes small employers and own- account workers,

lower supervisory and technical occu- pations, and semi-routine and routine occupations, never workers and long-term unemployed). We also assessed the number of quit attempts in the last year prior to the most recent attempt, time since the most recent quit attempt was initiated (either more or less than 6 months ago), whether smokers had tried to quit abruptly or gradually and the year of the survey.

Analysis

Bivariate associations between the use of different quit- ting methods and potentially

confounding socio- demographic and smoking history variables were assessed with χ^2 tests and one-way analyses of variance (ANOVA)s for categorical and continuous variables, respectively. Significant omnibus results were investi- gated further by *post*-*hoc* Sidak-adjusted χ^2 tests and *t*-tests.

Our measure of dependence (strength of urges to smoke) assumed that the score relative to other smokers would remain the same from pre- to post-quitting [32,33]. If a method of quitting reduced the strength of

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urges to smoke more than another method, this would tend to underestimate the effectiveness of that interven- tion because the smokers using this method would appear to be less dependent. To test for this bias, we used an analysis of covariance (ANCOVA) to examine whether the difference in strength of urges to smoke in smokers versus non-smokers depended upon the method of quit- ting, adjusting for the time since the quit attempt started.

In the analysis of the associations between quitting method and abstinence, we used a logistic regression model in which we regressed the outcome measure (self- reported nonsmoking compared with smoking) on the effect measure (use of e-cigarettes compared with either NRT bought over-the-counter or no aid). The primary analysis was an adjusted model that included the poten- tial confounders listed above and two interaction terms: (i) between time since last quit attempt and time spent with urges, and (ii) between time since last quit attempt of urges to smoke. These interaction terms were used to reflect the fact that urges to smoke following a quit attempt are influenced by whether an individual is currently abstinent and the duration of abstinence [32,33]. In addition to the model from the primary analy- sis ('fully adjusted model'; model 4), we constructed a simple model including only the effect measure ('unad- justed model'; model 1), a model that included the effect measure, year of the survey and all potential confounders except for the two measures of tobacco dependence, and a model that included all variables from the previous model and the two measures of tobacco dependence but without their interaction terms ('partially adjusted models'; models 2 and 3, respectively) to assess the extent of confounding by dependence. As *post-hoc* sensitivity analyses, the models were re-examined using different potential confounders from the ones specified a priori and reported in previous publications using the same meth- odology [32,33]. First, the time since the initiation of the quit attempt was included using the following six catego- ries: 'in the last week'; 'more than a week and up to a month'; 'more than 1 month and up to 2 months'; 'more than 2 months and up to 3 months'; 'more than 3 months and up to 6 months'; and 'more than 6 months and up to a year'. Secondly, an additional index of dependence—the heaviness of smoking index (HSI) [40]—was included. The HSI was assessed by asking current smokers to estimate current cigarettes per day and time to first cigarette (the two items comprising HSI) and by asking non-smokers to recall these behaviours prior to their quit attempt. Finally, in *post-hoc* subgroup analyses all models were repeated (i) among those report- ing smoking one or more than one cigarette per day (CPD) to determine whether inclusion of very light smokers might have had an influence on the results; (ii) among those completing the survey between 2012–14

once e-cigarette usage had become prevalent; and (iii) in the two subsamples of respondents who had started their most recent quit attempt less or more than 6 months ago, in order to assess the interplay between long-term effec- tiveness and the occurrence of differential recall bias. All analyses were performed with complete cases.

RESULTS

A total of 6134 respondents reported a most recent quit attempt in the last 12 months that was either unaided (n = 3477) or supported by NRT bought over-the-counter (n = 2095), e-cigarettes (n = 489) or both (n = 73). Those using both were excluded as were those using a prescrip- tion stop-smoking medication or face-to-face behavioural support in combination with either NRT bought over-the- counter (n = 173) or e-cigarettes (n = 25). Thus, the study population consisted of 5863 smokers who had made an attempt to quit in the previous year, of whom 7.9% (464) had used e-cigarettes, 32.8% (1922) had used NRT bought over-the-counter and 59.3% (3477) had used no aid to cessation. Quitting method did not differ by sex or the number of quit attempts in the past year but was associated with age, social grade, time since the quit attempt started, CPD, smoking less than one CPD, the measures of dependence (time with and strength of urges and HSI) and whether the attempt had begun abruptly (see Table 1). The post-hoc comparisons showed that those who used either e-cigarettes or no aid were younger than those using NRT over-the-counter, and that those who used NRT over-the-counter or no aid were more likely to hold a lower social grade than those using e-cigarettes. As would be expected, given the recent advent of e-cigarettes, the quit attempts of e-cigarette users were less likely to have begun more than 6 months previously than those using NRT over-thecounter or no aid. Those using NRT bought over-the-counter smoked more cigarettes and scored higher than either of the other two groups on all measures of dependence. Ecigarette users smoked more cigarettes, and were more dependent by the strength of urges measure and HSI than those using no aid. Finally, those using no aid were more likely to have smoked less than one CPD and stopped abruptly than the other two groups.

Strengths of urges to smoke were higher in smokers than in non-smokers (see Table 2).

However, the mean differences in strength of urges between smokers and non-smokers were similar across method of quitting: the interaction between smoking status (smokers versus non- smokers) and method of quitting in an ANCOVA of the strength of urges adjusted for the time since quit attempt started was not significant (F(2, 5856) = 1.50, P = 0.22).

Non-smoking was reported among 20.0% (93 of 464) of those using e-cigarettes, 10.1% (194 of 1922) using

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Real-world effectiveness of e-cigarettes 1535 **Table 1** Associations between characteristics of the sample and use of different quitting methods.

Mean (SD) age% (*n*) Female% Social grade C2DEMean (SD) cigarettes per day \Im % (*n*) < 1 cigarettes per day \Im % (*n*) Time since quit attempt started >26 weeks Mean (SD) quit attempts in the past yearMean (SD) time spent with urges to smoke (0–5) Mean (SD) strength of urges to smoke (0–5)Mean (SD) heaviness of smoking index[†]% (*n*) Abrupt attempt (no gradual cutting down first)

E-cigarettes (n = 464)

39.0 (15.6)^a 47.2 (219) 59.3 (275)^{cd} 12.6 (8.0)^{ef}

0.7 (3)^h 23.7 (110)^{jk}

 $1.6\ (0.9)\ 1.9\ (1.3)^l\ 2.0\ (1.2)^{no}\ 2.0\ (1.5)^{qr}$

50.4 (234)^t

NRT over-the-counter (n = 1922)

41.2 (15.3)^{ab} 51.1 (982) 65.9 (1266)^c 13.8 (8.5)^{eg}

 $0.8 (15)^{i} 36.4 (700)^{j} 1.6 (0.9)$

 $2.2 (1.3)^{lm} 2.2 (1.1)^{np} 2.3 (1.5)^{qs} 52.5 (1010)^{u}$

No aid(n = 3477) P

37.5 (16.2)^b *** 48.9 (1699) NS 65.5 (2277)^d * 10.9 (8.1)^{fg} ***

 $2.8 (94)^{hi} *** 36.5 (1269)^{k} *** 1.5 (0.9) \text{ NS } 1.8 (1.3)^{m} *** 1.8 (1.1)^{op} *** 1.6 (1.5)^{rs}$

Different pairs of superscript letters indicate a significant difference (P < 0.05) between two groups after Sidak adjustment for multiple comparisons. *P < 0.05; ***P < 0.001; NS = not statistically significant ($P \ge 0.05$). §A subgroup of those using nicotine replacement therapy (NRT) over-the-counter provided information about the form of NRT (n = 975): 60.0% (585) used a patch, 21.0% (205) gum, 14.9% (145) an inhalator, 6.2% (60) lozenges, 1.2% (12) microtabs and 1.0% (10) nasal spray. NB: response options were not mutually exclusive and 11.1% (108) reported using more than one form. ¶Data were missing for 156 respondents (e-cigarettes: 22; NRT over-the-counter: 34; no aid: 100). †Data were missing for 172 respondents (e-cigarettes: 23; NRT over-thecounter: 36; no aid: 113). SD = standard deviation.

Table 2 Differences between smokers and non-smokers in strength of urges to smoke by method of quitting.

Method of quitting n

E-cigarettes 371 NRT over-the-counter 1728 No aid 2942

Mean (SD) strength of urgesto smoke in smokers n

2.3 (1.1) 93 2.3 (1.0) 194 2.0 (1.0) 535

Mean (SD) strength of urges to smoke in non-smokers

0.8 (1.1) 1.2 (1.3) 0.7 (1.1)

Mean difference (95% CI) in strength of urges to smoke

1.4 (1.2–1.7) 1.2 (1.0–1.3) 1.3 (1.2–1.4)

NB: the mean differences are calculated from exact rather than the rounded figures presented in columns 3 and 5 of this table. The mean difference in strength of urges to smoke was not different across the methods of quitting (F(2, 5856) = 1.50, P = 0.22 for the interaction term between smoking status and method of quitting adjusted for the time since the quit attempt started). SD = standard deviation; CI = confidence interval; NRT = nicotine replace- ment therapy.

NRT over-the-counter and 15.4% (535 of 3477) using no aid. The unadjusted analyses indicated that e-cigarette users were more likely to be abstinent than either those using NRT bought over-the-counter [odds ratio (OR) = 2.23,95% confidence interval (CI) = 1.70-2.93) or those who used no aid (OR = 1.38,95% CI = 1.08-1.76; see model 1, Table3). The primary analyses revealed that the fully adjusted odds of non-smoking in

users of e-cigarettes were 1.63 (95% CI = 1.17-2.27) times higher compared with users of NRT bought over- the-counter and 1.61 (95% CI = 1.19-2.18) times higher compared with those using no aid (see model 4, Table 3). The relative magnitudes of the ORs from the fully adjusted model with the other three unadjusted and par- tially adjusted models illustrate the confounding effects of dependence (see Table 3).

In *post-hoc* sensitivity analyses, the associations between quitting method and nonsmoking were re-examined using models including different potential confounders. In a model including the more fine-grained assessment of time since the initiation of the quit attempt

than the measure presented in Table 1, the adjusted odds of non-smoking in users of ecigarettes were 1.58 (95% CI = 1.13-2.21) times higher compared with users of NRT bought over-the-counter and 1.55 (95% CI = 1.14-2.11) times higher compared with those using no aid. In another model that included another measure of dependence (HSI; missing data 3%, n = 172), the adjusted odds of non-smoking in users of e-cigarettes were 1.63 (95% CI = 1.15-2.32) times higher compared with users of NRT bought overthe-counter and 1.43 (95% CI = 1.03-1.98) times higher compared with those using no aid.

In *post-hoc* subgroup analyses, very light smokers were shown to have little influence on the pattern of results: in repeated analyses among those 5595 smokers reporting smoking one or more than one CPD the adjusted odds of non-smoking in users of e-cigarettes were higher compared with users of NRT bought over- the-counter (OR = 1.59,95% CI = 1.13-2.26) and com- pared with those using no aid (OR = 1.63,95% CI = 1.18-2.24). Similarly, the exclusion of respondents

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1536 Jamie Brown et al. Table 3 Associations between quitting method and abstinence.

Full sample (n = 5863) % (n) Self-reported

non-smoking

Subsample: quit attempt % (*n*) Self-reported

non-smoking

Subsample: quit attempt % (*n*) Self-reported

non-smoking

(1) e-Cigarettes

20.0 (93/464)

(2) NRT over-the-counter

10.1 (194/1922)

(3) No aid

15.4 (535/3477)

14.6 (323/2208)

16.7 (212/1269)

(1) versus (2)Model 1: OR (95% CI) Model 2: OR (95% CI) Model 3: OR (95% CI) Model 4: OR (95% CI)

2.23 (1.70-2.93)*** 1.88 (1.40-2.52)*** 1.63 (1.17-2.28)** 1.63 (1.17-2.27)**

(1) versus (3)Model 1: OR (95% CI) Model 2: OR (95% CI) Model 3: OR (95% CI) Model 4: OR (95% CI)

1.38 (1.08–1.76)* 1.21 (0.92–1.58) 1.62 (1.19–2.19)** 1.61 (1.19–2.18)**

started ≤ 26 weeks (*n* = 3784) 20.3 (72/354) 11.0 (135/1222)

started >26 weeks (*n* = 2079) 19.1 (21/110) 8.4 (59/700)

1.49 (1.12-1.98)** 1.39 (1.01-1.90)* 1.88 (1.32-2.68)***

Model 1 = unadjusted; model 2 = adjusted for age, sex, social grade, time since quit attempt started, quit attempts in the past year, abrupt versus gradual quitting and year of the survey; model 3 = adjusted for the variables from model 2 and time spent with urges to smoke and strength of urges to smoke; model 4 = adjusted for the variables from model 3 and the interaction terms time since last quit attempt started × time spent with urges and time since last quit attempt started × strength of urges to smoke. NB: for the two subsample analyses, model 4 is redundant, as there is no variation in the time since quit attempt. *P < 0.05; **P < 0.01; ***P < 0.001. OR = odds ratio; CI = confidence interval; NRT = nicotine replacement therapy.

during a time when e-cigarette usage was relatively rare (2009–11) had little effect on the results: among those 2306 smokers responding between 2012–14 the adjusted odds of non-smoking in users of e-cigarettes were higher compared with users of NRT bought over- the-counter (OR = 1.59, 95% CI = 1.05-2.42) and those using no aid (OR = 1.46, 95% CI = 1.04-2.05). In a final subgroup analysis the models were re-examined among those who started their quit attempt more or less than 6 months ago: there was only evidence among those who began their attempts less than 6 months ago of higher odds of non-smoking in users of e-cigarettes com- pared with users of NRT bought over-the-counter or those using no aid in the fully adjusted models (see Table 3).

DISCUSSION

Respondents who reported having used an e-cigarette in their most recent quit attempt were more likely to report still not smoking than those who used NRT bought over- thecounter or nothing. This difference remained after adjusting for time since the quit attempt started, year of the survey, age, gender, social grade, abrupt versus gradual quitting, prior quit attempts in the same year and a measure of nicotine dependence.

The unadjusted results have value in that they dem- onstrate self-reported abstinence is associated with quit-

ting method among those who use these methods to aid cessation in real-world conditions. However, this was not a randomized controlled trial and there were differences in the characteristics of those using different methods. For example, more dependent smokers tended to be more likely to use treatment, and smokers from lower social grades were less likely to use e-cigarettes. Although the adjustments go beyond what is typically undertaken in these types of real-world studies [28,29,41-44], it was not possible to assess all factors that may have been asso- ciated with the self-selection of treatment and we cannot rule out the possibility that an unmeasured confounding factor is responsible for the finding. For example, motiva- tion to quit is likely to have been associated positively with the use of treatment. However, previous population studies have found that the strength of this motivation is not associated with success of quit attempts once started, so it is unlikely to explain our findings [45]. There are other variables which are typically related to abstinence that may also be related to the selection of treatment; for example, those using e-cigarettes may have been less likely to share their house with other smokers, had better mental health or greater social capital of a kind not measured by social grade. These possibilities mean the associations reported here must be interpreted with caution. Nevertheless, the data provide some evidence in forming a judgement as to whether the advent of e-cigarettes in the UK market is likely to be having a

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2.06 (1.50–2.82)*** 1.80 (1.27–2.55)*** 1.56 (1.06–2.29)* — 2.56 (1.49–4.42)*** 1.98 (1.11–3.53)**1.64 (0.83–3.24) — 1.18 (0.72–1.94) 0.91 (0.54–1.55) 1.10 (0.59–2.06)

positive or negative impact on public health, in a way that a randomized controlled trial is unable to do.

The finding that smokers who had used an e-cigarette in their most recent quit attempt were more likely to report abstinence than those who used NRT bought over-the-counter, and that the latter did not appear to give better results than not using any aid [33], contrib-

utes to the debate about how far medicine regulation can go in ensuring that products used for smoking cessation are or continue to be effective in the real world [14–17]. Randomized controlled trials are clearly important in identifying potential efficacy, but real-world effectiveness will depend upon a number of other contextual variables. The current study, together with previous randomized trials, suggests that e-cigarettes may prove to be both an efficacious and effective aid to smoking ces- sation [10,11]. In so far that this is true, e-cigarettes may substantially improve public health because of their widespread appeal [6–9] and the huge health gains asso- ciated with stopping smoking [46]. This has to be offset against any detrimental effects that may emerge, as the longterm effects on health have not yet been estab- lished. However, the existing evidence suggests the asso- ciated harm may be minimal: the products contain low levels of carcinogens and toxicants [3] and no serious adverse event has yet been reported in any of the numer- ous experimental studies. Regardless, the harm will certainly be less than smoking, and thus of greater importance is the possible long-term effect of e-cigarettes on cigarette smoking prevalence beyond helping some smokers to quit. For example, it has been suggested that e-cigarettes might re-normalize smoking, promote experimentation among young people who otherwise may not have tried smoking or lead to dual use together with traditional cigarettes, and thereby deter some smokers from stopping [47]. The current data do not address these issues. However, the rise in e-cigarette prevalence in England since 2010 has coincided with continued reduction in smoking prevalence [48].

If e-cigarette use is proving more effective than NRT bought over-the-counter, a number of factors may con- tribute to this [49]. A greater similarity between using e-cigarettes and smoking ordinary cigarettes in terms of the sensory experience could be one factor. Greater novelty is another. It is also possible that users of e-cigarettes use their products more frequently or for a longer period than those using NRT without professional support. These are all issues that need to be examined in future research.

This study was not designed to assess the comparative effectiveness of e-cigarettes and NRT or other medica- tions obtained on prescription or behavioural support. The evidence still favours the combination of behavioural support and prescription medication as providing the

greatest chance of success [33,34,37], which is currently offered free at the point of access by the NHS stop smoking services in the United Kingdom.

A major strength of the current study is the use of a large, representative sample of the English population. Additionally, the study benefits from having begun to track the use of e-cigarettes as an aid to cessation at a time when e-cigarettes were only an emerging research issue. The importance of adjusting for nicotine depend- ence in real-world studies of smoking cessation is illus- trated by the difference in the ORs between the models with and without this adjustment. The optimal method of adjusting for dependence would be to assess this in all participants prior to their quit attempt. However, in a wholly cross-sectional study, we believe the particular method used to adjust for dependence, established in two previous studies, is valid [32,33]. One of the most commonly used alternative measures of dependence — HIS—relies upon the

number of cigarettes smoked and time to first cigarette of the day [40]. When smokers relapse they tend to do so with reduced consumption, which can lead to a false estimation of prior dependence in cross-sectional studies. This potential confound was avoided in the primary analysis by using a validated measure involving ratings of current urges to smoke and statistical adjustment of the urges for the time since the quit attempt was initiated [39]. The value of strength of urges as a measure of dependence in crosssectional research would be limited if different methods of stopping were linked differentially to lower or higher levels of urges in abstinent compared with relapsed smokers. For example, a method of stopping that led to a relatively higher reduction in urges could underestimate the effectiveness of that method by making it seem that those using it were less dependent. However, we have not previously found evidence in this population data set that urges to smoke in smokers versus quitters differs as a function of method [33], and it was true again in this study. Regardless, the pattern of results remained the same in both a sensitivity analysis that also included HSI and in a subgroup analysis that excluded very light smokers. It is unlikely, therefore, that differential dependence between the users of different treatments has led to a substantial over- or underestimation of the relative effectiveness of e-cigarettes in the current study. Nevertheless, future studies may be able to draw stronger inferences by including a broader array of dependence measures or assessing dependence prior to a quit attempt.

The study had several limitations. First, abstinence was not verified biochemically. In randomized trials, this would represent a serious limitation because smokers receiving an active treatment often feel social pressure to report abstinence. However, in population surveys the

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social pressure and the related rate of misreporting is low and it is generally considered acceptable to rely upon self- reported data [38]. A related issue is the assessment of abstinence by asking respondents whether they were 'still not smoking'. This definition classified as abstinent those who had one or more lapses but resumed not smoking. This limitation would be serious if the rate of lapsing was associated with method of quitting, and should be assessed in future studies. By contrast, advantages of this measure were the assessment of prolonged abstinence, as advocated in the Russell Standard, and a clear relation- ship to the quit attempt in question. An alternative approach, with a view to survival analysis, may have been to assess the length of abstinence since quit date among all respondents, including those who had relapsed by the time of the survey. However, this assessment would have added noise and potential bias with smokers needing to recall the time of relapse and having different interpretations of their return to smoking (i.e. first lapse, daily but reduced smoking, or smoking at pre-quit level). The strength of our approach is that smokers only needed to know whether they were currently still not smoking.

Secondly, there was a reliance upon recall data. The assessment of the most recent quit attempt involved recall of the previous 12 months and introduced scope for bias. The bias associated with recall of failed quit attempts would be expected to reduce the apparent effectiveness of reported aids to cessation because quit attempts using such aids would be more salient than those that were unaided [31]. Therefore, recall bias should militate against finding a benefit of e-cigarettes compared with no aid to cessation. Consistent with this explanation, the effect size for e-cigarettes compared with no aid appeared lower in smokers who started their quit attempt more than 6 months ago than in smokers who started their quit attempt less than 6 months ago. Although the power to detect the associations in these subgroups was limited, the explanation that the lack of effect in the more distant attempts was related to differential recall bias is also sup- ported by the absolute rate of non-smoking being higher in those making unaided attempts more than 6 compared with less than 6 months ago. Alternatively, the finding may reflect a reduced long-term effectiveness of e-cigarettes. Future longitudinal studies of e-cigarettes as aids to cessation in the general population may differen- tiate these explanations and would represent a valuable improvement upon the current study.

Thirdly, NRT over-the-counter and e-cigarettes both represent heterogeneous categories. In particular, there is considerable variability in nicotine vaporization between different types of e-cigarette [50,51]. Similarly, the simple definition of using one or the other aid to support an attempt is likely to have masked variability in how heavily, frequently and how long either NRT over-the-counter or

e-cigarettes were used by different smokers [12,52–54]. It is also possible that there were differences between the groups in their experience of unanticipated side effects. It is precisely because of all these factors—type/brand of NRT over-the-counter or e-cigarette, intensity and fre- quency of usage and experience of unanticipated side effects—that it is important to examine real-world effec- tiveness. However, it also means that we cannot make more exact statements about relative effectiveness of dif- ferent products and ways in which they may be used. Given this huge variability it may be many years before one could accumulate enough real-world data to address these questions. Finally, the prevalence of e-cigarettes has been increasing in England over the study period and this may affect real-world effectiveness. Although the evidence does not yet suggest an 'early adopters' effect—the current results persisted after adjusting for the year of survey and in a subgroup analysis limiting the data to a period when e-cigarette usage had become prevalent—these findings will need to be revisited to establish whether or not the apparent advantage of e-cigarettes is sustained.

In conclusion, among smokers trying to stop without any professional support, those who use e-cigarettes are more likely to report abstinence than those who use a licensed NRT product bought over-the-counter or no aid to cessation. This difference persists after adjusting for a range of smoker characteristics such as nicotine dependence.

Declaration of interests

All authors have completed the Unified Competing Inter- est form at http://www.icmje.org/coi_disclosure.pdf (available on request from the corresponding

author) and declare: JB's post is funded by a fellowship from the UK Society for the Study of Addiction; R.W. is funded by Cancer Research UK; Cancer Research UK, the Depart- ment of Health and Pfizer funded data collection for this study (including a Pfizer investigator initiated award), and that at the outset data collection for the Smoking Toolkit Study was also supported by GlaxoSmithKline and Johnson and Johnson; J.B., D.K. and E.B. have all received unrestricted research grants from Pfizer; R.W. undertakes research and consultancy and receives fees for speaking from companies that develop and manufac- ture smoking cessation medications (Pfizer, J&J, McNeil, GSK, Nabi, Novartis and Sanofi-Aventis); there are no other financial relationships with any organizations that might have an interest in the submitted work in the previous 3 years, particularly electronic cigarette compa- nies, and there are no other relationships or activities that could appear to have influenced the submitted work. Funding was provided for the conduct of this research and preparation of the manuscript. The funders had no

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final role in the study design; in the collection, analysis and interpretation of data; in the writing of the report; or in the decision to submit the paper for publication. All researchers listed as authors are independent from the funders and all final decisions about the research were taken by the investigators and were unrestricted.

Transparency declaration

J.B. affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained.

STROBE statement

All authors declare that study hypotheses arose before any inspection of the data and that all STROBE recom- mendations were followed.

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<u>SB1032</u> Submitted on: 2/25/2015 Testimony for WAM on Feb 27, 2015 13:00PM in Conference Room 211

Submitted By Organization		Testifier Position	Present at Hearing
Javier Mendez-Alvarez	Individual	Support	No

Comments:

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<u>SB1032</u> Submitted on: 2/25/2015 Testimony for WAM on Feb 27, 2015 13:00PM in Conference Room 211

Submitted By	Organization	Testifier Position	Present at Hearing
Tai Erum	Individual	Oppose	No

Comments:

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<u>SB1032</u> Submitted on: 2/26/2015 Testimony for WAM on Feb 27, 2015 13:00PM in Conference Room 211

Submitted By	Organization	Testifier Position	Present at Hearing
Justin Wolery	Individual	Oppose	No

Comments: Although vapor products contain NO tobacco, often times contain NO nicotine, and ultimately emit NO smoke, SB1032 aims to unfairly classify all vapor products as "Tobacco Products" to bring vapor products into the same regulatory framework as traditional tobacco cigarettes. This will have very dire unintended consequences and threatens to decimate the vapor industry in Hawaii. This could have far-reaching negative consequences and would set terrible precedent for future legislation.

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Re: Opposition to SB1032

Hearing: WAM, Friday, February 27, 2015 1:00 PM

I oppose SB1032. Vapor products contain NO tobacco, often contain NO nicotine, and ultimately emit NO smoke, so it is wrong to classify all vapor products as "Tobacco Products" to bring them into the same regulatory framework as traditional tobacco cigarettes. This will have dire unintended consequences on public health and will threaten to decimate the vapor industry in Hawaii.

Furthermore, adding a tobacco licensing requirement to non-tobacco businesses only increases the chances of those businesses deciding to sell tobacco, which should not be viewed as a positive development.

Thank you for your time and consideration.

P Kuromoto Honolulu, HI

Re: Opposition to SB1032

Hearing: WAM, Friday, February 27, 2015 1:00 PM

I oppose SB1032. Vapor products contain NO tobacco, often contain NO nicotine, and ultimately emit NO smoke, so it is wrong to classify all vapor products as "Tobacco Products" to bring them into the same regulatory framework as traditional tobacco cigarettes. This will have dire unintended consequences on public health and will threaten to decimate the vapor industry in Hawaii.

Thank you for your time and consideration.

Alika Spahn Naihe Kalihi, HI

Re: Opposition to SB1032

Hearing: WAM, Friday, February 27, 2015 1:00 PM

I oppose SB1032. Vapor products contain NO tobacco, often contain NO nicotine, and ultimately emit NO smoke, so it is wrong to classify all vapor products as "Tobacco Products" to bring them into the same regulatory framework as traditional tobacco cigarettes. This will have dire unintended consequences on public health and will threaten to decimate the vapor industry in Hawaii.

Thank you for your time and consideration.

michael Locey Kauai HI

Re: Opposition to SB1032

Hearing: WAM, Friday, February 27, 2015 1:00 PM

I oppose bill SB1032.

Thank you for your time and consideration.

Cynthia Howder

Re: Opposition to SB1032

Hearing: WAM, Friday, February 27, 2015 1:00 PM

I oppose SB1032. Vapor products contain NO tobacco, often contain NO nicotine, and ultimately emit NO smoke, so it is wrong to classify all vapor products as "Tobacco Products" to bring them into the same regulatory framework as traditional tobacco cigarettes. This will have dire unintended consequences on public health and will threaten to decimate the vapor industry in Hawaii.

Electronic cigarettes do not omit toxins or dangerous second-hand smoke into the air as tobacco products do. The 'smoke' is vapor and although scented is not harmful, short or long-term. The e-liquid that is used with e-cigs and vaporized is made out of three main ingredients, Propylene Glycol, Vegetable Glycerin, and added artificial/natural flavoring. All ingredients are FDA approved and do not exceed recommended dosage of consumption.

Thank you for your time and consideration.

Niki Kue

<u>SB1032</u> Submitted on: 2/26/2015 Testimony for WAM on Feb 27, 2015 13:00PM in Conference Room 211

Submitted By	Organization	Testifier Position	Present at Hearing
Jake J. Watkins	Individual	Oppose	No

Comments:

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